

Testing new neck artery stents designed to safely trap atherosclerotic plaque and heal the artery

Submission date 14/12/2025	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/12/2025	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 17/12/2025	Condition category Circulatory System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Stent healing, as assessed by strut coverage, is a key parameter for optimizing the duration of "double" antiplatelet therapy (DAPT) in patients after stent implantation. Data on the micronet stent healing are lacking.

The aim of this study is to evaluate the strut coverage of MicroNET-covered CGuard stents by optical coherence tomography (OCT) at 1-3 months after implantation.

Who can participate?

Consecutive patients implanted with the micronet-covered stent (CGuard) in the carotid artery, who have indication to another (staged) endovascular intervention performed at 1, 2, or 3 months after the index carotid artery treatment

What does the study involve?

The study involves assessment of stent strut coverage using intravascular Optical Coherence Tomography ("an intravascular light transducer camera") imaging. OCT is routinely used as the modality of choice to evaluate stents.

What are the possible benefits and risks of participating?

Patients may benefit from identifying lack of stent healing or strut malapposition; this may trigger appropriate treatment.

Possible risks are associated with target vessel cannulation and contrast injection. However, in the study patients, the vascular access, catheterisation and contrast are, anyway, indicated and performed for a concomitant endovascular intervention.

Where is the study run from?

The study is run from a university research center, experienced in carotid and other endovascular interventions and in OCT imaging. (Jagiellonian University, Poland)

When is the study starting and how long is it expected to run for?

The study started in November 2024 and is expected to run till 31 December 2026.

Who is funding the study?

The study is funded by a research grant from the Jagiellonian University (Poland)

Who is the main contact?

Piotr Musialek, MD DPhil

Jagiellonian University Professor of Cardiovascular Medicine

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof Piotr Musialek

ORCID ID

<https://orcid.org/0000-0001-9300-4833>

Contact details

80 Pradnicka St

KRAKÓW

Poland

31-202

+48 126143399

pmusialek@szpitaljp2.krakow.pl

Additional identifiers

Protocol serial number

N41/DBS/001562

Study information

Scientific Title

Healing Profile of the micronet-covered AtheRomA-isolating carotid stents Deployed for optimised Guard against cerebral embolisM: Optical Coherence Tomography Study

Acronym

PARADIGM-OCT

Study objectives

To evaluate the strut coverage of MicroNET-covered CGuard stents by optical coherence tomography (OCT) at 1-3 months after implantation.

Ethics approval required

Ethics approval required

Ethics approval(s)

Primary study design

Observational

Study design

Single-centre prospective observational longitudinal study

Study type(s)

Efficacy

Health condition(s) or problem(s) studied

Prevention of stroke in patients with carotid atherosclerosis treated with an innovative stent type

Interventions

In patients treated with micronet-covered stents for primary or secondary stroke prevention of carotid-related stroke, Optical Coherence Tomography (OCT) observation of stent coverage will be carried out at the point of another endovascular treatment performed at 1, 2 or 3 months after stent implantation.

Intervention Type

Other

Primary outcome(s)

Percentage of struts covered at 1, 2, or 3-months after stent implantation measured using Optical Coherence Tomography (OCT)

Key secondary outcome(s)

Percentage of struts malapposed at 1, 2, or 3-months after stent implantation measured using Optical Coherence Tomography (OCT)

Completion date

31/12/2026

Eligibility

Key inclusion criteria

Consecutive patients implanted with the micronet-covered stent (CGuard) in the carotid artery, who have indication to another (staged) endovascular intervention performed at 1, 2, or 3 months after the index carotid artery treatment.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Lack of indication to staged endovascular treatment following index carotid artery stenting with the Micronet-covered stent
2. Lack of consent

Date of first enrolment

02/12/2024

Date of final enrolment

31/12/2026

Locations**Countries of recruitment**

Poland

Study participating centre

Jagiellonian University Dept. of Cardiac & Vascular Diseases

St. John Paul II Hospital

80 Pradnicka St.

Krakow

Poland

31-202

Sponsor information**Organisation**

Jagiellonian University Medical College

Funder(s)

Funder type

Not defined

Funder Name

Uniwersytet Jagielloński Collegium Medicum

Alternative Name(s)

Jagiellonian University Medical College

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Poland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon reasonable request from the Principal Investigator (pmusialek@szpitaljp2.krakow.pl)

IPD sharing plan summary

Available on request